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TITLE: Race, Treatment, and Cardiovascular Health: A Study of Men With Prostate Cancer

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CONTRACTING ORGANIZATION: Henry Ford Health System,

Detroit, MI 48202

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13. SUPPLEMENTARY NOTES

14. ABSTRACT **As more men live with their prostate cancer, they face increased risk of cardiovascular disease (CVD); this risk is intensified by treatment type, in particular androgen deprivation therapy (ADT). There is a paucity of data exploring the risk of CVD among minority men with prostate cancer overall or by treatment type. We conducted a preliminary analysis examining pre and post diagnosis cholesterol profiles among men with prostate cancer, overall and by race and treatment type, using electronically available data on 2000 cases (1000 each African American and Caucasian). Pre-diagnosis, 1077 men (54%) had ≥1 cholesterol level measured and post-diagnosis, 1489 men (74%) had ≥1 cholesterol level measured. After adjusting for first measured cholesterol, there was evidence for a race by ADT interaction with change in cholesterol level (*P*=0.06). Compared to Caucasians never on ADT, both Caucasian and African-American men ever on ADT had an increase in cholesterol (1.6±1.5 mg/dL and 2.5±1.5 mg/dL, respectively), whereas African-American men never on ADT had a decrease in cholesterol (-1.33 mg/dL). ADT increased cholesterol levels in both African-American and Caucasian men with prostate cancer suggesting a need for guidelines for regular screening of men treated with ADT.**

15. SUBJECT TERMS
Prostate Cancer, survivorship, cardiovascular disease, health disparities.

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Introduction

Racial differences in the overall health of men living with prostate cancer are an important but understudied area of research. As more men live with their prostate cancer, they face increased risk of cardiovascular disease (CVD) events; this risk is intensified by treatment type. There is a paucity of data exploring the risk of CVD among minority men with prostate cancer overall or by treatment type. As African Americans, in general, are less likely to have CVD risk factors under control and are more likely to experience CVD events, we are (1) examining if African-American men with prostate cancer are more likely to have worsening CVD risk factor profiles and more CVD events than Caucasian men with prostate cancer during a follow-up period of 5 years past diagnosis and (2) examining if androgen deprivation therapy for prostate cancer is associated with worsening CVD risk factor profiles and more CVD events during a follow-up period of 5 years past diagnosis, and to determine whether race modifies these associations. This is a retrospective cohort study of men newly diagnosed with prostate cancer at Henry Ford Health System between years 1998 and 2006. As men undergoing prostate cancer treatment interface with the medical care system, there are considerable opportunities to assess their CVD factor profiles. If African-American men with prostate cancer are more likely to have worsening CVD risk factor profiles and to experience CVD events than their Caucasian counterparts, this could reveal an important and modifiable opportunity to reduce a disparity in the overall health of men with prostate cancer. Although treatment type may be associated with CVD risk factor changes and events, to-date only one study has examined this association in African-Americans. Results from this investigation will be used to identify the need to couple therapy with risk factor monitoring and will stimulate future research into potential underlying causes for these disparities.

Body

As outlined in the approved statement of work, the following tasks have been completed: obtained Human Subjects Regulatory Board Approval; obtained and maintained Henry Ford Health System Institutional Review Board Approval for Human Subject Research; created Access database for direct medical record abstraction data entry; created, piloted and revised medical record abstraction tool (see appendix); created electronic cohort of 2,000 prostate cancer cases (1,000 each African-American and Caucasian); developed and implemented quality control procedures; created database for study and database management is on-going; and all addresses have been geocoded to determine neighborhood-level socioeconomic status indicators.

As described in the statement of work training activities include completing the following course Epid 787 "An Introduction to Multilevel Analysis in Public Health" at the University of Michigan in July, 2010. This course covered analysis techniques that will be needed for analyzing the geocoded SES variables that are being collected for the current study. Additionally, the PI has regularly attended the HMORN Cancer Research Network annual meeting. The PI has submitted an abstract for the upcoming second Innovative Minds in Prostate Cancer Today (IMPaCT) conference, which has been accepted for poster presentation in March, 2011.

As described in the statement of work, detailed chart abstraction is ongoing. Death record searches will begin in mid-2011.

Preliminary analyses have begun using the electronically obtained data on the cohort of 2,000 men. In cross-sectional studies, Androgen Deprivation Therapy (ADT) is associated with cholesterol levels[1] and ADT may also be associated with worsening risk factor profiles.[2] We

examined the relationship of ADT use (ever/never) with total cholesterol level pre- and post-diagnosis (see abstract in the appendix).

The analytic sample consisted of 2000 prostate cancer cases (1000 each African American and Caucasian) identified from the Henry Ford Health System tumor registry. African-American and Caucasian prostate cancer cases were age (+/- 5 years) and date of diagnosis (+/- 1 year) matched. Information on cholesterol levels 1 year prior to diagnosis to 5 years post-diagnosis and ADT use (ever/never) were obtained from electronic corporate data stores at Henry Ford Health System. Linear mixed models were fit to examine whether there was a racial difference in change in cholesterol level, adjusting for first measured cholesterol, by ADT.

A total of 7528 cholesterol measures were available. Pre-diagnosis, 1077 men (54%) had ≥1 cholesterol level measured and post-diagnosis, 1489 men (74%) had ≥1 cholesterol level measured. After diagnosis, there was a racial difference in number of men with cholesterol measures by ADT use ($P<0.001$); among those ever using ADT, more African-American men had ≥1 cholesterol measure, while among those never using ADT, more Caucasian men had ≥1 cholesterol measure. After adjusting for first measured cholesterol, there was evidence for a race by ADT interaction with change in cholesterol level ($P=0.06$). Compared to Caucasians never on ADT, both Caucasian and African-American men ever on ADT had an increase in cholesterol whereas African-American men never on ADT had a decrease in cholesterol (Table 1).

Table 1: Change in cholesterol level by Androgen Deprivation Therapy (ADT) and race

	C / No ADT	AA / No ADT	C / ADT	AA / ADT	P-Value
		Est (SE)	Est (SE)	Est (SE)	
Cholesterol	Ref	-1.33 (1.13)	1.64 (1.50)	2.52 (1.52)	0.0661

C, Caucasian; AA, African-American; Est, Estimate; SE, standard error; Ref, referent category

To our knowledge, this is the first investigation examining change in cholesterol levels by ADT use and race, adjusted for baseline cholesterol levels. Given that the 1-year pre-diagnosis time frame only yielded 54% with a baseline cholesterol level, we obtained IRB approval to obtain the most recent pre-diagnosis cholesterol level not restricting to the 1 year time period, which improves our ability to adjust for baseline cholesterol levels in this cohort. These preliminary analyses are continuing, and we plan to refit our models adjusting for the additional baseline cholesterol levels, as well as CVD medication use and an indicator variable for number of visits with a healthcare provider to our models.

Key Research Accomplishments

- Cholesterol profile of men with prostate cancer varies by race and treatment type. This abstract was submitted and accepted for poster presentation to the IMPaCT meeting.

Reportable Outcomes

Cassidy-Bushrow, AE. Mahan, M. Rybicki BA. Cholesterol profile of men with prostate cancer varies by race and treatment type. 2011. Accepted for poster presentation at second Innovative Minds in Prostate Cancer Today (IMPaCT) conference, Orlando, FL, March 2010.

Conclusions

In our study population of men with prostate cancer, most had cholesterol screening at least once within the 5-years post-diagnosis. As demonstrated by others, ADT was associated with an increase in cholesterol level. However, cholesterol monitoring overall was lacking among those ever on ADT, predominantly in the Caucasian group, demonstrating a potential gap in CVD risk factor monitoring in a high-risk group. Given that ADT increased cholesterol levels in both African American and Caucasian men with prostate cancer, guidelines for regular screening of men treated with ADT may be warranted. Additional work planned as part of this study includes examination of pre- and post diagnosis of hypercholesterolemia, use of cholesterol-lowering medications, and the role of additional cardiovascular risk factors (e.g. hypertension, diabetes) on risk of events in this population of African-American and Caucasian prostate cancer cases.

References

1. Braga-Basaria M, Muller DC, Carducci MA, Dobs AS, Basaria S. Lipoprotein profile in men with prostate cancer undergoing androgen deprivation therapy. *Int J Impot Res*. 2006;18:494-498.

2. Smith MR, Lee H, McGovern F, Fallon MA, Goode M, Zietman AL, Finkelstein JS. Metabolic changes during gonadotropin-releasing hormone agonist therapy for prostate cancer: differences from the classic metabolic syndrome. *Cancer*. 2008;112:2188-2194.

Appendices

Appendix I. Current medical chart abstraction tool

Race, Androgens and Cardiovascular Health (RACH): A Study of Men with Prostate Cancer

1.a. Study ID _____
1.b. MRN: _____
1.c. Patient Name: _____ _____

2. Date of Abstraction _____/_____/____
3. Code of Abstractor _____
4. Date of Birth ____/_____/____

5. Date of prostate cancer diagnosis: _____/_____/____

5.a. Based on date of prostate cancer diagnosis, compute the abstraction range as 1 year prior to diagnosis to 5 years past diagnosis: _____ to _____

6. Race
Caucasian or White □
African American or Black □

7. Marital Status at Diagnosis
Married or Living as Married □
Not Married □
Single (never married) □
Divorced/Legally Separated □
Widowed □
NOT FOUND □
Other □ If Other, Please specify: _____

8. Address _____
City _____ State_____ ZIPCode_____

9. Insurance Status Yes □ No □

10. Employment Status: please circle:

full-time
part-time
retired
unemployed
disabled
employed but unknown FT or PT

11. Usual Occupation _____

12. Previous Cancers (other than prostate)
site:_____ date of diagnosis____/_____/_____
site:_____ date of diagnosis____/_____/_____

13. Family history of (Please include relative type, if mentioned):

Prostate Cancer □ Comment _____
Other Cancer □ Specify _____
Comment _____
Hypertension □ Comment _____
High Cholesterol □ Comment _____
Diabetes □ Comment _____
Heart Disease □ Specify _____
Comment _____

14. Date of last visit to HFHS: _____

15. If the patient did not have a visit to HFHS ON OR AFTER (date of diagnosis + 5 years), do the records indicate the patient died: Yes □ No □ Unknown □
if Yes, Date of Death _____
Cause of Death _____

16. Other Diseases (please record <u>all</u> indications before diagnosis and up to 5 years past diagnosis; for hypertension, high cholesterol, diabetes, BPH, prostatitis and PIN, please mark the 1st occurrence):

Heart Disease

MI/heart attack ((specify STEMI (Q-wave MI) or non-STEMI (non Q MI)) Yes □ No □
Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____
Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____

Angina (please specify stable or unstable) Yes □ No □
Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____
Type_____
date of diagnosis_____/_____/____

Type_____
date of diagnosis____/_____/____

Heart failure Yes □ No □
date of diagnosis____/_____/____

Stroke,(please specify ischemic, intracerebral hemorrhage, subarachnoid hemorrhage); Yes □ No □

Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____
Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____

Other Cardiovascular: (Please specify: dysrhythmias; conduction disorders; valve disease; valve repair/replacement; cardiac arrest; cardiomyopathy): Yes □ No □

Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____
Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____

Cardiovascular procedures/devices (please specify: Revascularization, coronary angiography/catheterization; CABG, Implantable cardiodefribillator (ICD); pacemaker; PCI) Yes □ No □

Type_____
date of procedure_____/_____/____
Type_____
date of procedure ____/_____/____
Type_____
date of procedure _____/_____/____
Type_____
date of procedure ____/_____/____

Hypertension/High Blood Pressure: Yes □ No □ date of diagnosis_____/_____/____

High cholesterol: Yes □ No □ date of diagnosis____/_____/____

Type I Diabetes: Yes □ No □ date of diagnosis____/_____/____

Type II Diabetes: Yes □ No □ date of diagnosis____/_____/____

Benign Prostatic Hyperplasia: Yes □ No □ date of diagnosis____/_____/____

Prostatitis : Yes □ No □ date of diagnosis____/_____/____

PIN : Yes □ No □ date of diagnosis____/_____/____

Kidney Disease (consider acute renal failure, chronic renal failure; dialysis) Yes □ No □

Type_____
date of diagnosis_____/_____/____
Type_____
date of diagnosis____/_____/____

Peripheral vascular disease Yes □ No □ date of diagnosis____/_____/____

Other Chronic Conditions (consider autoimmune diseases (e.g. lupus, multiple sclerosis) and any condition that may impact mobility (e.g. wheel-chair bound)) (Specify condition and where possible, date of
diagnosis:_____
_____
_____

17. Prostate Cancer Characteristics (Please use data obtained closest to original diagnosis; use comments to denote if multiple methods used to fill in this section):

Primary Gleason Score (highest noted) From BIOPSY: _____ Date: ___/_____/____

Secondary Gleason Score (highest noted) From BIOPSY: _____Date: ____/____/___

Primary Gleason Score (highest noted) From Prostatectomy: _____ Date: __/__/__

Secondary Gleason Score (highest noted) From Prostatectomy: _____ Date: __/__/__

Tumor Grade (if no Gleason score): _____ Date: ____/_____/_____

Tumor Stage (highest noted):
T status: _____ Date: ____/_____/_____
N status: _____ Date: ____/_____/_____
M status _____ Date: ____/_____/_____

Tumor size ____cm. x _____cm. x _____cm.

If prostatectomy, please note prostate weight: _____ grams

Prostate gland volume (obtained via TRUS): ____cm. x _____cm. x _____cm. (i.e. width x height x length)

Method of detection: _____

Method of diagnosis: _____

Symptoms: _____

Comments: _____

18. Treatment characteristics (up to 5 years past diagnosis):

Did the patient have radiation therapy (RT)? Yes □ No □

If yes, please complete for each round of RT (if unknown, please mark unknown):

Date Started	**Date Ended**	**Dose**	**Frequency (# of days)**	**Details/Comments**

Did the patient have Brachytherapy (BT)? Yes □ No □

If yes, please complete for each round of BT (if unknown, please mark unknown):

Date Started	**Date Ended**	**Dose**	**Frequency (# of days)**	**Details/Comments**

Did the patient have orchiectomy? Yes □ No □ IF Yes, date: ___/____/_____

Did the patient have Hormone Therapy (HT)? Yes □ No □

If yes, please complete for each round of HT (if unknown, please mark unknown):

Type of Hormone	**Date Started**	**Date Ended**	**Dose**	**Frequency (# of days)**	**Details/Comments**

Did the patient have any other therapy types? Yes □ No □

If yes, please complete for each round (if unknown, please mark unknown):

Other Therapy	**Date Started**	**Date Ended**	**Dose**	**Frequency (# of days)**	**Details/Comments**

Were there any side-effects of treatment noted (please consider cardiac arrest, respiratory arrest, hospitalization, myocardial infarction, cardiac arrhythmia, stroke, deep venous thrombosis, hypotension, **hypertension,** congestive heart failure, hot flashes, fatigue, loss of muscle, loss of bone mass)

_____

_____
_____
_____

Were any herbal or alternative remedies noted: Yes □ No □

Describe: _____
_____
_____

19. Please list all PSA results and dates from one year before diagnosis to 5 years after diagnosis:

PSA Result	Date	PSA Result	Date

20. History of cigarette smoking:

Before diagnosis: Never □ Former □ Current □ Unknown □
If Former, when Quit: MM/DD/YYYY or Age _____
If Current, how much does the patient smoke:_____

In the five year period following diagnosis: Never □ Former □ Current □ Unknown □
If Former, when Quit: MM/DD/YYYY or Age _____
If Current, how much does the patient smoke:_____

Comments on post-diagnosis smoking (e.g. attempts to quit, etc…) :_____
_____

21. Patient Height: _____ft _____ inches Date: ____/_____/_____

22. Please list all weights (and units of measure) available from 1 year prior to diagnosis to 5 years past diagnosis:

Weight (units)	Date	Weight (units)	Date

23. Please list all Lipid Measurements 1 year prior to diagnosis to 5 years past diagnosis (only include fasting tests):

Cholesterol	HDL-C	LDL-C	Triglycerides	Date

24. Please list all Blood Pressure Measurements 1 year prior to diagnosis to 5 years past diagnosis:

Systolic BP	Diastolic BP	Date	Type of visit (PCP, oncologist, urologist, ER, other)

25.a. Please list all fasting glucose, insulin levels, or C-reactive protein (CRP) in 1 year prior to diagnosis to 5 years past diagnosis:

Fasting glucose	Date	Insulin	Date	CRP	Date

25.b. Please list all Hemoglobin A1c values from 1 year prior to diagnosis to 5 years past diagnosis.

HbA1c	Date

26. Please list all medications used in the 1 year prior to diagnosis until the 5 years past diagnosis:

Medication Name	**Dosage**	**Frequency of Use**	**Units of Frequency of use**	**Date Prescribed**	**Reason for Prescription**
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month	__ __ / __ __ / __ __	

			As needed		
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	
			Per day Per week Per month As needed	__ __ / __ __ / __ __	

27. Did the patient have a primary care visit for a physical examination during the 5 years since prostate cancer diagnosis?

If Yes, please record the date of each physical exam visit.

For each visit, were the following measured/tests ordered:

Weight: (Yes)(No)(Unknown)
Blood Pressure: (Yes)(No)(Unknown)
Fasting Lipids: (Yes)(No)(Unknown)
Fasting glucose/insulin/or HbA1C: (Yes)(No)(Unknown)

28. Please circle at the time of diagnosis, whether the patient used alcohol:

No/Almost no Consumption (<1 drink/month)
Mild (~1-3 drinks per month)
Moderate (~4-14 drinks per month)
Heavy (> 14 drinks per month)
Yes, use, but quantity unknown

29. Please list all available Ejection Fractions from 1 year prior to diagnosis to 5 years past diagnosis.:

Ejection Fraction	Date

30. Please list all available Serum Creatinine and glomerular filtration rate values from 1 year prior to diagnosis to 5 years past diagnosis.:

Serum Creatinine	GFR	Date

31. ACE-27

At the time of diagnosis, please check if the following conditions are present.

Adult Comorbidity Evaluation-27

Identify the important medical comorbidities and grade severity using the index. Overall Comorbidity Score is defined according to the highest ranked single ailment, except in the case where two or more Grade 2 ailments occur in different organ systems. In this situation, the overall comorbidity score should be designated Grade 3.

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Cardiovascular System			
Myocardial Infarct	☐ MI ≤ 6 months	☐ MI > 6 months ago	☐ MI by ECG only, age undetermined
Angina / Coronary Artery Disease	☐ Unstable angina	☐ Chronic exertional angina ☐ Recent (≤ 6 months) Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) ☐ Recent (≤ 6 months) coronary stent	☐ ECG or stress test evidence or catheterization evidence of coronary disease without symptoms ☐ Angina pectoris not requiring hospitalization ☐ CABG or PTCA (>6 mos.) ☐ Coronary stent (>6 mos.)
Congestive Heart Failure (CHF)	☐ Hospitalized for CHF within past 6 months ☐ Ejection fraction < 20%	☐ Hospitalized for CHF >6 months prior ☐ CHF with dyspnea which limits activities	☐ CHF with dyspnea which has responded to treatment ☐ Exertional dyspnea ☐ Paroxysmal Nocturnal Dyspnea (PND)
Arrhythmias	☐ Ventricular arrhythmia ≤ 6 months	☐ Ventricular arrhythmia > 6 months ☐ Chronic atrial fibrillation or flutter ☐ Pacemaker	☐ Sick Sinus Syndrome ☐ Supraventricular tachycardia
Hypertension	☐ DBP≥130 mm Hg ☐ Severe malignant papilledema or other eye changes ☐ Encephalopathy	☐ DBP 115-129 mm Hg ☐ DBP 90-114 mm Hg while taking antihypertensive medications ☐ Secondary cardiovascular symptoms: vertigo, epistaxis, headaches	☐ DBP 90-114 mm Hg while not taking antihypertensive medications ☐ DBP <90 mm Hg while taking antihypertensive medications ☐ Hypertension, not otherwise specified
Venous Disease	☐ Recent PE (≤ 6 mos.) ☐ Use of venous filter for PE's	☐ DVT controlled with Coumadin or heparin ☐ Old PE > 6 months	☐ Old DVT no longer treated with Coumadin or Heparin
Peripheral Arterial Disease	☐ Bypass or amputation for gangrene or arterial insufficiency < 6 months ago ☐ Untreated thoracic or abdominal aneurysm (≥6 cm)	☐ Bypass or amputation for gangrene or arterial insufficiency > 6 months ago ☐ Chronic insufficiency	☐ Intermittent claudication ☐ Untreated thoracic or abdominal aneurysm (< 6 cm) ☐ s/p abdominal or thoracic aortic aneurysm repair
Respiratory System			
	☐ Marked pulmonary insufficiency ☐ Restrictive Lung Disease or COPD with dyspnea at rest despite treatment ☐ Chronic supplemental O_2 ☐ CO_2 retention (pCO_2 > 50 torr) ☐ Baseline pO_2 < 50 torr ☐ FEV1 (< 50%)	☐ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnea which limits activities ☐ FEV1 (51%-65%)	☐ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnea which has responded to treatment ☐ FEV1 (66%-80%)
Gastrointestinal System			
Hepatic	☐ Portal hypertension and/or esophageal bleeding ≤ 6 mos. (Encephalopathy, Ascites, Jaundice with Total Bilirubin > 2)	☐ Chronic hepatitis, cirrhosis, portal hypertension with moderate symptoms "compensated hepatic failure"	☐ Chronic hepatitis or cirrhosis without portal hypertension ☐ Acute hepatitis without cirrhosis ☐ Chronic liver disease manifested on biopsy or persistently elevated bilirubin (>3 mg/dl)
Stomach / Intestine	☐ Recent ulcers(≤ 6 months ago) requiring blood transfusion	☐ Ulcers requiring surgery or transfusion > 6 months ago	☐ Diagnosis of ulcers treated with meds ☐ Chronic malabsorption syndrome ☐ Inflammatory bowel disease (IBD) on meds or h/o with complications and/or surgery
Pancreas	☐ Acute or chronic pancreatitis with major complications (phlegmon, abscess, or pseudocyst)	☐ Uncomplicated acute pancreatitis ☐ Chronic pancreatitis with minor complications (malabsorption, impaired glucose tolerance, or GI bleeding)	☐ Chronic pancreatitis w/o complications

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Renal System			
End-stage renal disease	☐ Creatinine > 3 mg% with multi-organ failure, shock, or sepsis ☐ Acute dialysis	☐ Chronic Renal Insufficiency with creatinine >3 mg% ☐ Chronic dialysis	☐ Chronic Renal Insufficiency with creatinine 2-3 mg%.
Endocrine System	**(Code the comorbid ailments with the (*) in both the Endocrine system and other organ systems if applicable)**		
Diabetes Mellitus	☐ Hospitalization ≤ 6 months for DKA ☐ Diabetes causing end-organ failure ☐ retinopathy ☐ neuropathy ☐ nephropathy* ☐ coronary disease* ☐ peripheral arterial disease*	☐ IDDM without complications ☐ Poorly controlled AODM with oral agents	☐ AODM controlled by oral agents only
Neurological System			
Stroke	☐ Acute stroke with significant neurologic deficit	☐ Old stroke with neurologic residual	☐ Stroke with no residual ☐ Past or recent TIA
Dementia	☐ Severe dementia requiring full support for activities of daily living	☐ Moderate dementia (not completely self-sufficient, needs supervising)	☐ Mild dementia (can take care of self)
Paralysis	☐ Paraplegia or hemiplegia requiring full support for activities of daily living	☐ Paraplegia or hemiplegia requiring wheelchair, able to do some self care	☐ Paraplegia or hemiplegia, ambulatory and providing most of self care
Neuromuscular	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder and requiring full support for activities of daily living	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but able to do some self care	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but ambulatory and providing most of self care
Psychiatric			
	☐ Recent suicidal attempt ☐ Active schizophrenia	☐ Depression or bipolar disorder uncontrolled ☐ Schizophrenia controlled w/ meds	☐ Depression or bipolar disorder controlled w/ medication
Rheumatologic	**(Incl. Rheumatoid Arthritis, Systemic Lupus, Mixed Connective Tissue Disorder, Polymyositis, Rheumatic Polymyositis)**		
	☐ Connective Tissue Disorder with secondary end-organ failure (renal, cardiac, CNS)	☐ Connective Tissue Disorder on steroids or immunosuppressant medications	☐ Connective Tissue Disorder on NSAIDS or no treatment
Immunological System	**(AIDS should not be considered a comorbidity for Kaposi's Sarcoma or Non-Hodgkin's Lymphoma)**		
AIDS	☐ Fulminant AIDS w/KS, MAI, PCP (AIDS defining illness)	☐ HIV+ with h/o defining illness. $CD4^+ < 200/\mu L$	☐ Asymptomatic HIV+ patient. ☐ HIV^+ w/o h/o AIDS defining illness. $CD4^+ > 200/\mu L$
Malignancy	**(Excluding Cutaneous Basal Cell Ca., Cutaneous SCCA, Carcinoma in-situ, and Intraepithelial Neoplasm)**		
Solid Tumor including melanoma	☐ Uncontrolled cancer ☐ Newly diagnosed but not yet treated ☐ Metastatic solid tumor	☐ Any controlled solid tumor without documented metastases, but initially diagnosed and treated within the last 5 years	☐ Any controlled solid tumor without documented metastases, but initially diagnosed and treated > 5 years ago
Leukemia and Myeloma	☐ Relapse ☐ Disease out of control	☐ 1st remission or new dx <1yr ☐ Chronic suppressive therapy	☐ H/o leukemia or myeloma with last Rx > 1 yr prior
Lymphoma	☐ Relapse	☐ 1st remission or new dx <1yr ☐ Chronic suppressive therapy	☐ H/o lymphoma w/ last Rx >1 yr prior
Substance Abuse	**(Must be accompanied by social, behavioral, or medical complications)**		
Alcohol	☐ Delirium tremens	☐ Active alcohol abuse with social, behavioral, or medical complications	☐ H/o alcohol abuse but not presently drinking
Illicit Drugs	☐ Acute Withdrawal Syndrome	☐ Active substance abuse with social, behavioral, or medical complications	☐ H/o substance abuse but not presently using
Body Weight			
Obesity		☐ Morbid (i.e., BMI ≥ 38)	

OVERALL COMORBIDITY SCORE (Circle one.)	**0** **None**	**1** **Mild**	**2** **Moderate**	**3** **Severe**	**9** **Unknown**

32. Please check here if abstraction is complete: ☐

Appendix II. Abstract submitted and accepted for IMPaCT meeting

Title: Cholesterol profile of men with prostate cancer varies by race and treatment type

Authors: Andrea E. Cassidy-Bushrow, PhD[1]; Meredith Mahan, MS[1]; Benjamin A. Rybicki, PhD[1,2].

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Background and Objectives: As more men live with their prostate cancer, they face increased risk of cardiovascular disease (CVD); this risk is intensified by treatment type, in particular androgen deprivation therapy (ADT). Although African-American men are at increased risk of CVD in the general population, there is a paucity of data exploring the risk of CVD among minority men with prostate cancer overall or by treatment type. The purpose of the current study was to examine pre and post diagnosis cholesterol profiles among men with prostate cancer, overall and by race and treatment type.
Brief Description of Methodologies: The analytic sample consisted of 2000 prostate cancer cases (1000 each African American and Caucasian) identified from the Henry Ford Health System (HFHS) tumor registry. African-American and Caucasian prostate cancer cases were age (+/- 5 years) and date of diagnosis (+/- 1 year) matched. Information on cholesterol levels 1 year prior to diagnosis to 5 years post-diagnosis and ADT use (ever/never) were obtained from electronic corporate data stores at HFHS. Linear mixed models were fit to examine whether there was a racial difference in change in cholesterol level, adjusting for first measured cholesterol, by ADT.
Results to Date: A total of 7528 cholesterol measures were available. Pre-diagnosis, 1077 men (54%) had ≥1 cholesterol level measured and post-diagnosis, 1489 men (74%) had ≥1 cholesterol level measured. After diagnosis, there was a racial difference in number of men with cholesterol measures by ADT use ($P<0.001$); among those ever using ADT, more African-American men had ≥1 cholesterol measure, while among those never using ADT, more Caucasian men had ≥1 cholesterol measure. After adjusting for first measured cholesterol, there was evidence for a race by ADT interaction with change in cholesterol level ($P=0.06$). Compared to Caucasians never on ADT, both Caucasian and African-American men ever on ADT had an increase in cholesterol (1.6±1.5 mg/dL and 2.5±1.5 mg/dL, respectively), whereas African-American men never on ADT had a decrease in cholesterol (-1.33 mg/dL).
Conclusions: In this population of men with prostate cancer, most had cholesterol screening at least once within the 5-years post-diagnosis. As demonstrated by others, ADT was associated with an increase in cholesterol level. However, cholesterol monitoring overall was lacking among those ever on ADT, predominantly in the Caucasian group, demonstrating a potential gap in CVD risk factor monitoring in a high-risk group. Additional work planned as part of this study includes examination of pre- and post diagnosis of hypercholesterolemia, use of cholesterol-lowering medications, and the role of additional cardiovascular risk factors (e.g. hypertension, diabetes) on risk of events in this population of African-American and Caucasian prostate cancer cases.

Impact statement describing the potential impact on research, patient care or quality of life: Hyperlipidemia is a powerful predictor of CVD; in this patient sample, nearly 75% of men diagnosed with prostate cancer had at least 1 cholesterol measure after cancer diagnosis. Given that ADT increased cholesterol levels in both African American and Caucasian men with prostate cancer, guidelines for regular screening of men treated with ADT are warranted.